reagent in terms of reflectance of light entered into the reagent layer, wherein said reagent layer comprises polymer beads embedding light reflective particles, and a hydrophilic high molecular substance as main constituent of the matrix.

REMARKS

Claims 1-5 are pending in the above-identified patent application. Applicants have amended herein Claim 1. No new matter is contained in the amendments. Based on the foregoing amendments and the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

Rejections Under 35 U.S.C. § 102

The Examiner rejects Claims 1-5 under 35 U.S.C. § 102(b) as being clearly anticipated by *Koyama et al.* (U.S. Patent No. 4,430,436), *Terashima et al.* (U.S. Patent No. 4,839,278) or EP 162,302 on the grounds that all of the references teach test devices with a reagent layer having the claimed reflective layer in combination with the claimed polymer.

However, Applicants believe that the novelty of the present invention as claimed in Claims 1-5 should not be rejected by *Koyama et al.*, *Terashima et al.* or EP 162,302, as will be discussed below.

Present Invention

A dry measuring test device according to the present invention after amendment comprises a reagent layer comprising a reagent containing a chromogen and a matrix having the reagent in the form of a layer, for determining a substance to be measured in a liquid sample by measuring the degree of coloring of the chromogen generated through the reaction between the substance and the reagent in terms of reflectance of light entered into the reagent layer, wherein the reagent layer comprises polymer beads embedding light reflective particles, and a hydrophilic high molecular substance as main constituent of the matrix.

Conventionally, in this kind of dry measuring test device for determining a substance to be measured in a liquid sample through the coloring reaction between the substance to be measured and the reagent, in order to enhance measurement precision, an attempt was made to have the light reflective particles directly contained in the reagent layer and have the reagent for coloring contained therein as well. However, if a large amount of light reflective particles are contained to improve the measurement precision, the reagent layer becomes so dense that a liquid sample can hardly penetrate and develop, and it takes a long time until the amount of the coloring matter generated by the reaction with the reagent becomes sufficiently measurable. Thus, this is a problem in practical use. Further, it is disadvantageous in that the measurement precision may possibly be lowered due to dryness if the measuring time is prolonged as described above.

The dry measuring test device according to the present invention has a reagent layer that does not directly contain the light reflective particles, but the invention uses the polymer beads embedding light reflective particles to solve the problems described above. The dry measuring test device of the present invention can contain a large amount of light reflective particles in the reagent layer in the form of polymer beads, embedding them with such a structure that the measuring time is so short that influence of dryness can be reduced.

Differences between each of the cited references and the present invention

(i) As to Koyama et al. (U.S. Patent No. 4,430,436)

Koyama et al. discloses an invention related to an analytical element having an interconnected void structure zone comprising a plurality of heat-stable organic polymer particle units having reactive groups, and the particle units being chemically bonded directly to each other through the reactive groups. In analytical element of *Koyama et al.*, the void structure zone may contain an interactive composition which has the same meaning as reagent of the present invention and the interactive composition may be immobilized by physical adsorption or chemical bonding to the particles (see col. 11, lines 48-50 and col. 12, lines 24-26). Further, in col. 13, lines 34-37, there is a description that the polymer particle units may contain the radiation-blocking agents.

As described above, the interconnected void structure zone of Koyama's analytical element may become a porous reagent layer the matrix of which consists of the heat-stable organic polymer particle units. However, it can be said that the construction of the interconnected void structure zone in *Koyama et al.* is different from that of the reagent layer of the present invention after amendment which comprising a reagent, polymer beads embedding light reflective particles and a matrix which mainly consists of hydrophilic high molecular substance wherein the reagent and the polymer beads are retained in the matrix in the form of a layer.

It is obvious that the reagent layer in the dry measuring test device of the present invention does not have the porous structure, referring to the description of the producing process of the reagent layer in the present specification from page 21, line 16 to page 22, line 23. Though the reagent layer of the present invention is not porous, the matrix of the layer mainly consists of hydrophilic high molecular substance and, therefore a liquid sample can penetrate sufficiently rapidly into the reagent layer of the present invention.

Further, comparing the feature of the reagent layer between *Koyama et al.* and the present invention, the reagent layer of the present invention is softer than that in *Koyama et al.* because it is well known that the matrix made from hydrophilic high molecular substance is softer than that made from heat-stable organic polymer particles which are used in *Koyama et al.* It is advantageous if the sample includes the soft substance which is easy to be destroyed such as a blood cell.

Therefore, there is no description nor suggestion in *Koyama et al.* as to the construction of the reagent layer of the dry measuring test device of the present invention.

(ii) As to Terashima et al. (U.S. Patent No. 4,839,278)

Terashima et al. discloses an invention related to an integral multilayer analytical element for measurement of alkaline phosphatase activity. In *Terashima et al.* col. 9, lines 16-52 there is a description about an analytical element which has a light-blocking layer in which light-blocking (or light-reflecting) fine particles are dispersed in a small amount of a film-forming

hydrophilic polymer binder. From this description, it is clear that the light-blocking particles are dispersed in the form of the particles per se in the hydrophilic polymer film. Furthermore, the light-blocking layer described in *Terashima et al.* is an independent layer which is separated from the reagent layer. *Terashima et al.* also teaches that the light-blocking particles may be incorporated into the spreading layer.

However, there is no description in *Terashima et al.* of the reagent layer comprising polymer beads embedding light reflective particles used in the present invention, nor suggestion as to the construction of the reagent layer of the dry measuring test device of the present invention.

(iii) As to EP 162,302

EP 162,302 discloses an invention related to an integral multilayer analytical element. In EP 162,302, page 8, line 8 to page 9, line 20, there is a description about an analytical element which has a light-shielding layer in which light-shielding microparticles or light-shielding and light-reflecting microparticles (hereinafter referred as "light-shielding particles") are dispersed in a small amount of a film-forming hydrophilic polymer binder. From this description, it is clear that the light-shielding particles are dispersed in the form of the particles per se in the hydrophilic polymer film, Furthermore, the light-shielding layer described in EP 162,302 is an independent layer which is separated from the reagent layer.

However, there is no description in EP 162,302 of the reagent layer comprising polymer beads embedding light reflective particles used in the present invention, nor suggestion as to the construction of the reagent layer of the dry measuring test device of the present invention.

As discussed above, since *Koyama et al.* (U.S. Patent No. 4,430,436), *Terashima et al.* (U.S. Patent No. 4,839,278) or EP 162,302 do not disclose and suggest the construction of the reagent layer of the dry measuring test device of the present invention after amendment, Applicants believe the novelty of the present invention as claimed in Claims 1-5 should not be

rejected. Therefore, the rejection of Claims 1-5 under 35 U.S.C. § 102(b) should be reconsidered and withdrawn.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 10-1215.

The foregoing is submitted as a full and complete Response to the Office Action mailed November 13, 1998. This Response places all claims in the present application in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

NOTICE OF CHANGE OF CORRESPONDENCE ADDRESS

Please note that the correspondence address for the above-referenced patent application has been changed to:

Jones & Askew, LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
Telephone: 404-949-2400

Respectfully submitted,

JONES & ASKEW, LLP

By: William L. Warren
Reg. No. 36,714

2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
(404) 949-2400
Our Docket: 20111-0014